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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/577,657 | 05/25/2000 | Misako Mizuno | 029430-454 | 6902 |

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EXAMINER

KUBELIK, ANNE R

ART UNIT PAPER NUMBER

1638

DATE MAILED: 09/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/577,657

Applicant(s)

MIZUNO ET AL.

Examiner

Anne R. Kubelik

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 June 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 29-31,33-36 and 38-55 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 29-31,33-36 and 38-55 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 29-31, 33-36 and 38-55 are pending.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. The objection to claim 51 under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim is withdrawn in light of applicant's amendment of the claim.
4. The objection to claims 54-55 under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only is withdrawn in light of applicant's amendment of the claim.
5. The objection to claims 29-34 because there is an improper article before "N-methyl" in line 2 is withdrawn in light of applicant's amendment of the claims.

Claim Objections

6. Claim 54 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 30. When two claims in an application are duplicates or else are so in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 112

7. Claims 29-31, 34-36 and 39-53 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for nucleic acids of SEQ ID NO:2 and plant cells and

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plants transformed with those nucleic acids, does not reasonably provide enablement for nucleic acids that encode SEQ ID NO:1 or nucleic acids that have 90% identity to any nucleic acid that encodes SEQ ID NO:1 or for RNA vectors and plants transformed therewith. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The rejection is repeated for the reasons of record as set forth in the Office action mailed 17 February 2004. Applicant's arguments filed 17 June 2004 have been fully considered but they are not persuasive.

Applicant urges that one of ordinary skill in the art can readily make and determine the activity of DNAs and RNAs comprising SEQ ID NO:1 (response pg 11-12).

This is not found persuasive because the rejection is lack of enablement for using the nucleic acid, given that SEQ ID NO:1 is not the entire protein sequence. Kato et al (2000, Nature 406:956-957) teach a gene encoding a caffeine synthase that is identical to the caffeine synthase of the instant invention except the published enzyme is 13 amino acids longer at its N-terminal (see sequence search results sent with the Office action of 16 October 2001). All experiments involving transformation used a DNA comprising SEQ ID NO:2, which is almost identical to the nucleic acid taught by Kato et al and would encode the full-length enzyme. The specification does not teach how to use a nucleic acid encoding only a portion of the enzyme.

Applicant urges that the skilled artisan could produce the claimed modified sequences and determine where they have the desired enzyme activity; any experimentation required would not be undue (response pg 12).

This is not found persuasive because making all possible single amino acid substitutions in a 356 amino acid long protein like that encoded by SEQ ID NO:2 would require making and analyzing 19^{356} nucleic acids. Nucleic acids with 90% identity to the portion of SEQ ID NO:2 that encodes SEQ ID NO:1 would be at least 1068 nucleotides long and would have up to 106 nucleotides substitutions compared to that portion of SEQ ID NO:2; this would mean that the proteins encoded by these nucleic acids could encode a protein with 106 amino acid substitutions compared to SEQ ID NO:1; these proteins would have only 70.2% identity to SEQ ID NO:1. The specification does not teach nucleic acids that encodes proteins with N3-methyl transferase, theobromine N1 methyl transferase and paraxanthine N3 methyl transferase activities and that have 70.2% identity to SEQ ID NO:1. Nucleic acids with 90% identity to any nucleic acid that encodes SEQ ID NO:1 would encode proteins even more amino acid substitutions compared to SEQ ID NO:1, and the specification does not teach any of these nucleic acids. As the specification does not provide guidance for these nucleic acids, undue trial and error experimentation would be required to screen through the myriad of nucleic acids encompassed by the claims, if such nucleic acids are even obtainable.

Applicant urges that SEQ ID NO:1 is the mature enzyme sequence acting in tea leaves; Kato et al used the precursor coding sequence (response pg 12-14).

This is not found persuasive because the portion cleaved from the precursor may have function required for activity in plant cells. For example that portion may be required for targeting the enzyme to the proper cellular compartment for function.

Claims 45-48 are drawn to any plant transformed with the claimed nucleic acid. However, few plant species would have the enzyme required to produce the substrate for the

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enzyme of SEQ ID NO:1 and few would have a nucleic acid whose expression could be silenced by a nucleic acid encoding SEQ ID NO:1. Thus, it is not clear how one would use any plant transformed with a nucleic acid encoding SEQ ID NO:1.

Furthermore, neither the specification nor the prior art teaches how to transform any member of the *Coffea* or *Camellia* genera. *Coffea* includes *C. abeokutae*, *C. arabica*, *C. arnoldiana*, *C. aruwimiensis*, *C. bertrandi*, *C. brevipes*, *C. canephora*, *C. congensis*, *C. costatifructa*, *C. dolichophylla*, *C. eugenioides*, *C. excelsa*, *C. farafanganensis*, *C. humblotiana*, *C. humilis*, *C. kapakata*, *C. khasiana*, *C. liberica*, *C. millotii*, *C. perrieri*, *C. pseudozanguebariae*, *C. racemosa*, *C. resinosa*, *C. sakarahae*, *C. salvatrix*, *C. sessiliflora*, *C. stenophylla*, and *C. zanguebariae*, while *Camellia* includes *C. achrysantha*, *C. albogigas*, *C. chrysanthoides*, *C. fascicularis*, *C. flavida*, *C. fusuiensis*, *C. grandis*, *C. granthamiana*, *C. grijsii*, *C. henryana*, *C. huana*, *C. impressinervis*, *C. japonica*, *C. lanceolata*, *C. liberofilamenta*, *C. limonia*, *C. longgangensis*, *C. longruiensis*, *C. longzhouensis*, *C. micrantha*, *C. multipetala*, *C. nitidissima*, *C. parvipetala*, *C. petelotii*, *C. pingguoensis*, *C. ptilosperma*, *C. pubipetala*, *C. salicifolia*, *C. sasanqua*, *C. sinensis*, *C. terminalis*, *C. tunghinensis*, *C. xiashiensis*, and *C. yunnanensis*. Transformation of only a few of these species is possible.

As the specification does not describe the isolation of any nucleic acid other than SEQ ID NOs:2-3 or the transformation of any plant with any nucleic acid other than SEQ ID NO:2, undue trial and error experimentation would be required to screen through the myriad of nucleic acids encompassed by the claims and plants transformed therewith, to identify those nucleic acids that encode proteins with N3-methyl transferase, theobromine N1 methyl transferase and paraxanthine N3 methyl transferase activities, if such enzymes are even obtainable and those

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plants with altered concentrations of caffeine, xanthine, paraxanthine or theobromine, if such plants are even obtainable.

8. Claims 29-31, 34-36 and 39-53 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The rejection is repeated for the reasons of record as set forth in the Office action mailed 17 February 2004. Applicant's arguments filed 17 June 2004 have been fully considered but they are not persuasive.

Applicant urges that as detailed above with respect to the enablement requirement, one of ordinary skill in the art would agree they were in possession of the claimed subject matter (response pg 14).

This is not found persuasive because the specification does not teach the structural features, *i.e.*, the sequence, of a single nucleic acid that has 90% identity to any nucleic acid that encodes SEQ ID NO:1 and that encodes a protein with N3-methyl transferase, theobromine N1 methyl transferase and paraxanthine N3 methyl transferase activities. The critical structural motifs that distinguish nucleic acids that encode functional enzymes from those that do not are not described.

9. Claims 49-51 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention. Dependent claims are included in all rejections. The rejection is repeated for the reasons of record as set forth in the Office action mailed 17 February 2004, as applied to claims

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30-31, 35-36, 40, 42, 44, 46, 48-49, 51 and 53. Applicant's arguments filed 17 June 2004 have been fully considered but they are not persuasive.

Claim 49, lines 5 and 6, and claim 50, lines 4 and 5, are indefinite in their recitation of "plant body". The specification defines "plant body" as "the whole individual organism classified into plant or organ parts thereof such as leaves, stems, roots, flowers, fruits, seeds and the likes" [sic]. Culturing a whole plant to form a plant body would therefore mean culturing a whole plant to form a whole individual plant; the phrase is redundant and meaningless.

Applicant urges that because the definition allows for organ parts and not simply the whole plant, the phrase "plant body" is neither redundant or meaningless" (response pg 15-16).

This is not found persuasive because the definition includes whole plants, and thus the claim is drawn to culturing a whole plant to form a whole individual plant. If organ parts are what is intended, then the language of the claim should reflect that.

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne R. Kubelik, whose telephone number is (571) 272-0801. The examiner can normally be reached Monday through Friday, 8:30 am - 5:00 pm.

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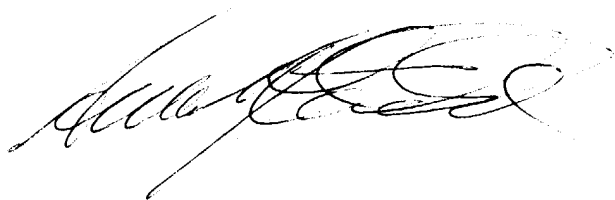
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at (571) 272-0804. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Anne R. Kubelik, Ph.D.
September 7, 2004



**ANNE KUBELIK
PATENT EXAMINER**